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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,494	05/08/2001	Ehud Goldin	3394/1H557US1	2229
7590 09/17/2004 DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022			EXAMINER ULM, JOHN D	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/851,494	Applicant(s) GOLDIN ET AL.	
	Examiner John D. Ulm	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 12-7, 33-5 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 12-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 33-35 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/29/04</u> . | 6) <input type="checkbox"/> Other: _____ |

1) Claims 1 to 7, 12 to 27, 33 to 35 and 39 are pending in the instant application. Claims 1, 2, 5, 12, 16, 20, and 33 have been amended, claims 8 to 11, 28 to 32 and 36 to 38 have been canceled and claim 39 has been added as requested by Applicant in the correspondence filed 21 June of 2004.

2) Claims 12 to 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the correspondence filed 29 September of 2003. Applicant is advised that the non-elected process claims will not be rejoined with the elected product claims until a product claim is indicated as allowable.

3) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5) Claims 2 to 5 and 33 to 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5.1) Claim 2 is vague and indefinite because there is no antecedent basis for "the gene". This claim is also vague and indefinite because the limitation "mutation" requires a point of reference and none is given.

5.2) Claim 3 is vague and indefinite because there is no antecedent basis for "the mutation".

5.3) Claim 4 is vague and indefinite because there is no antecedent basis for “the defect in expression”.

5.4) Claims 4, 5 and 33 to 35 are vague and indefinite because the metes and bounds of the limitation “MCOLN1” are undeterminable for those reasons of record in section 7.2 of the previous office action. Claims 6 and 7 are vague and indefinite in so far as they depend from claim 5 for this limitation.

6) Claims 1, 5 to 7, 33 to 35 and 39 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by the Curtis et al. publication (Pub. No. US 2002/0035056 A1) and the Lal et al. publication (Pub. No. US 2002/0182671 A1) for those reasons of record as applied to claims 1, 5 to 7 and 33 to 35 in section 8 of the previous office action. Applicant’s argument that these references did not disclose or suggest the incorporation of the nucleic acids described therein into a pharmaceutical composition is not persuasive. Applicant is advised that water constitutes a pharmaceutically acceptable carrier and each of these references taught the dissolution of the nucleic acids described therein in water.

The Declaration filed on 21 June of 2004 under 37 CFR 1.131 has been considered but is ineffective to overcome the Curtis et al. and the Lal et al. references because it was not executed by the inventor of the claimed subject matter (see M.P.E.P. 715.04(I)(A) and it did not state that the activities described therein were completed in the United States, a NAFTA country, or a WTO member country as required by 37 CFR 1.131.

7) Applicant's arguments filed 21 June of 2004 have been fully considered but they are not persuasive.

8) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kunz Gary can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1646

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN ULM
PATENT EXAMINER
GROUP 1200